# GOVERNMENT OF INDIA
# CHEMICALS AND FERTILIZERS
# LOK SABHA

UNSTARRED QUESTION NO:6420
ANSWERED ON:09.05.2005
WITHDRAWAL OF VALDECOXILE PAIN KILLER
Purandeswari Smt. Daggubati

**Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:**

(a) whether Valdecoxile,a pain-killer used widely by arthritic patients has been withdrawn from the U.S.markets under Food and Drug Administration (FDA);

(b) if so, the details thereof and the reasons therefor;

(c) whether the same medicine is still in circulation in Indian markets;

(d) if so, whether the Govt. proposes to withdraw the said medicine from markets; and

(e) if not, the reasons therefor?

## Answer

THE MINISTER OF CHEMICALS AND FERTILIZERS AND MINISTER OF STEEL (SHRI RAM VILAS PASWAN):

(a) and (b) Yes, Sir. Valdecoxib, a pain killer indicated for arthritis and acute pain, marketed in USA under the brand name Bextra by M/s. Pfizer Inc. has been withdrawn by the manufacturer on the advice of the US FDA, as the drug has been found to be associated with increased risk of serious skin reactions.

(c) to (e) In the light of the withdrawal of the drug in USA, the continued use of Valdecoxib in the country has been examined by the National Pharmaco Vigilance Advisory Committee on 2.5.2005 and it has recommended that the drug may be prohibited for manufacture and sale in the country by the Government of India under the Drugs and Cosmetics Act.